Amendments to the Drawings:

The attached sheet of drawings includes changes to Figs. 1A and 1B. This sheet, which includes Figs. 1A and 1B, replaces the original sheet including Figs. 1A and 1B.

Attachment: Replacement Sheet

REMARKS/ARGUMENTS

In response to the Examiner's rejections, the claims and drawings have been amended as specified above. None of the amendments adds new matter.

Amendments in General

The drawings have been amended to more clearly show the expelling material to which reference number 50 points in Figs. 1A and 1B.

Claims 1 and 9 have been amended to clarify that the calibrated puncturing device is "configured so as to not be attached to said ampule when dispensing" said quantity of medication or said suspension, as the case may be, from said ampule. Support for these amendments is found in the specification at paragraphs [0007], [0010], and [0023], among others, in conjunction with Figs. 1A, 1B, 2, and 3. Paragraph [0007] discusses that an "object of the invention is to provide such a medicine delivery and storage system that is predosed and easy to deliver so as to allow by an individual with little or no medical training to adequately and appropriately administer the medication." Paragraph [0010] states that, as to administering the medication, "[t]o use the device the container is opened the ampule removed, agitated or mixed . . . and then punctured by the puncturing device." Paragraph [0023] states that "[o]nce the opening 16 has been made in the ampule 12, the medication may be delivered by simply squeezing the ampule 12 to force the medication out of the ampule 12 through the opening 16." Figs. 2 shows the ampule in position against the puncturing device. Fig. 3 shows the container having the puncturing portions without the ampule in the container. Figs. 1A and 1B show the ampule that, once already punctured to create the opening 16, may be squeezed to dispense the medication or suspension. Accordingly, the amendments to claims 1 and 9 do not add new matter because the specification describes that the calibrated puncturing device is "configured so as to not be attached to said ampule when dispensing" the quantity of medication or the suspension from the ampule.

Claims 1 and 9 have also been amended to clarify that the two references to openings or to an opening and to a hole are references to the same opening.

Claim 2 has been amended to remove the reference to "laterally" in the third line.

Claim 14 has been amended to remove a typographical error of a floating "l."

Drawings

The Examiner did not accept the drawings received by the Examiner on October 3, 2006, for the reason that the proposed drawings had an additional leader line from a reference number 50 pointing to the medication in a dry, powdered form (Fig. 1A) or in combination with a reconstituting liquid (Fig. 1B). Fig. 1A has been amended to more clearly show that the leader line from reference number 50 points to the expelling material of that embodiment, i.e., the air in the space between the particles of medication in a dry, powdered form. Fig. 1B has been amended to more clearly show the expelling material of the embodiment, i.e., air, which is now shown more clearly to be above the combination of medication and reconstituting liquid. The amended drawings add no new matter as it is understandable from the description of the invention that air is located between the bits of powdered material, as shown in Fig. 1A, and that when liquid, powdered material, and air mix in an enclosed environment, such as the ampule in Fig. 1B, the air, being the least dense material, will, at least initially, rise to the top of the ampule while the liquid and powdered material remain at the bottom, as is shown in Fig. 1B as amended.

The Examiner further objected to the drawings because they did not show "the squeezable propellant chamber" and "the expelling material." As previously discussed, Figs. 1A and 1B have been amended to more clearly show "the expelling material." In addition, the previously presented and current claims do not reference a "squeezable propellant chamber."

For the foregoing reasons, the Applicant respectfully requests acceptance of the drawings as amended, which the Applicant contends are nonobjectionable.

Specification Objections

The Examiner objected to the specification for the reason that the reference number "50" should be removed because the drawings of record did not have a reference number 50. Assuming that the Examiner accepts the drawings as amended, which the Applicant believes the Examiner will do, the drawings to be made of record include reference number "50"; therefore, the specification has not been amended to remove that reference number.

Claim Rejections – 35 U.S.C. § 112, second paragraph

The Examiner rejected claims 1–3, 6–11, and 14–16 under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter that applicant regards as the invention for the following two reasons.

First, the Examiner noted that claim 1 recited "an opening in said ampule" in line 6 and also recited "to create an opening of a desired size within said ampule" in lines 8 and 9, and stated that it was unclear as to whether these recitations were meant to refer to the same opening or to two different openings. Claim 1 has been amended such that it is clear that the recitations are meant to refer to the same opening.

Second, the Examiner noted that claim 9 recited "an opening of a calibrated size" in lines 11 and 12 and also recited "to produce a hole of a calibrated size within said ampule" in lines 14 and 15, and stated that it was unclear as to whether these recitations were meant to refer to the same opening or hole. Claim 9 has been amended such that it is clear that the recitations are meant to refer to the same opening.

For the foregoing reasons, the Applicant respectfully submits that claims 1–3, 6–11, and 14–16, in light of the amendments to claims 1 and 9, comply with 35 U.S.C. § 112, second paragraph.

Claim Rejections – 35 U.S.C. § 112, first paragraph

The Examiner rejected claims 1–3, 6–11, and 14–16 under 35 U.S.C. § 112, first paragraph, as failing to comply with the written description requirement for the following three reasons:

First, the Examiner stated that claim 1 recited "an opening in said ampule" in line 6 and also recited "to create an opening of a desired size within said ampule" in lines 8 and 9. The Examiner stated that if the recitations were meant to refer to two different openings, the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the application was filed, had possession of the claimed invention. As previously discussed, the two referenced recitations in claim 1 refer to the same opening, which is made clear in claim 1 as amended. Accordingly, the claimed subject matter was adequately described in the specification.

Second, the Examiner stated that claim 2 recited that the ampule is "laterally" compressed while the originally-filed specification was silent as to the direction of any compression. The reference to "laterally" has been removed from claim 2.

Third, the Examiner stated that claim 9 recited "an opening of a calibrated size" in lines 11 and 12 and also recited "to produce a hole of a calibrated size within said ampule" in lines 14 and 15. The Examiner stated that if the recitations were meant to refer to an opening and a different hole, then the claimed subject matter was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor, at the time the

application was filed, had possession of the claimed invention. As previously discussed, the two referenced recitations in claim 9 refer to the same opening, which is made clear in claim 9 as amended. Accordingly, the claimed subject matter was adequately described in the specification.

For the foregoing reasons, the Applicant respectfully submits that claims 1–3, 6–11, and 14–16, in light of the amendments to claims 1, 2, and 9, comply with 35 U.S.C. § 112, first paragraph.

Claim Rejections – 35 U.S.C. § 102

"An applicant for a patent is entitled to the patent unless the application fails to meet the requirements established by law. It is the Commissioner's duty (acting through the examining officials) to determine that all requirements of the Patent Act are met. The burden is on the Commissioner to establish that the applicant is not entitled under the law to a patent . . . . In rejecting an application, factual determinations by the PTO must be based on a preponderance of the evidence, and legal conclusions must be correct." *In re Oetiker,* 977 F.2d 1443, 1449, 24 USPQ2d 1443, 1447, 24 USPQ2d at 1447 (Fed. Cir. 1992) (Plager, J., concurring). Further, "[t]he precise language of 35 USC 102 that 'a person shall be entitled to a patent unless,' concerning novelty and unobviousness, clearly places a burden of proof on the Patent Office which requires it to produce the factual basis for its rejection of an application under sections 102 and 103." *In re Warner,* 379 F.2d 1011, 1016, 154 USPQ 173 (CCPA 1967), *cert. denied*, 389 U.S. 1057, *reh'g denied*, 390 U.S. 1000 (1968).

"A claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." *Verdegaal Bros. v. Union Oil Co. of Cal.*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). "The identical invention must be shown in as complete detail as contained in the . . . claim." *Richardson v. Suzuki Motor Co.*, 828 F.2d 1226, 1236, 9 USPQ2d 1913, 1920 (Fed. Cir. 1989). MPEP § 2131.

Claims 1–3, 6, 7, 9–11, 14, and 15

The Examiner rejected claims 1–3, 6, 7, 9–11, 14, and 15 under 35 U.S.C. § 102(b) as being anticipated by the capsule for dental restoration material described in U.S. Patent Number 6,386,872 (the Mukasa patent).

Claim 1, from which claims 2, 3, 6, and 7 depend, either directly or indirectly, and claim 9, from which claims 10, 11, 14, and 15 depend, either directly or indirectly, have been amended to include the limitation that the calibrated puncturing device be "configured so as to not be attached to said ampule when dispensing" said quantity of medication (claim 1) or said suspension (claim 9) from the ampule.

Mukasa describes a capsule for dental restoration material in which a plunger having a rod-like projection and that is engaged with a cylindrical portion within a liquid cup is used to break apertures while pushing dental restoration material out through a nozzle. However, because the plunger with rod-like projection is used to dispense the dental restoration material, Mukasa does not teach or suggest an oral liquid medication dispensing system in which a calibrated puncturing device is "configured so as to not be attached to said ampule when dispensing" a quantity of medication or a suspension from the ampule. To the contrary, the plunger with rod-like projection is necessarily attached to the "ampule" of the Mukasa device at the time of dispensing because it required to push out the material being dispensed from the Mukasa "ampule." Accordingly, each and every element of claims 1 and 9 as amended, and therefore claims 2, 3, 6, 7, 10, 11, 14, and 15, are not found in the Mukasa reference. Accordingly, the Applicant respectfully contends that, in light of the amendments to claims 1 and 9, Mukasa does not anticipate claims 1–3, 6, 7, 9–11, 14, or 15.

Claim Rejections - 35 U.S.C. § 103

Obviousness Analysis Pursuant to *KSR Int'l Co. v. Teleflex Inc.*, 550 U.S. (Apr. 30, 2007)

As the United States Supreme Court recently confirmed in *KSR International Co. v. Teleflex Inc.*, 550 U.S. ____ (Apr. 30, 2007), since its announcement in 1966, *Graham v. John Deere* has provided the controlling framework for an obviousness analysis under the patent law. Accordingly, a proper obviousness analysis requires a *Graham v. Deere* analysis rather than reliance on the old "*prima facie* case" test of *In re Vaeck*. Thus, it remains necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. Further, in order to determine whether there was an apparent reason to combine known prior art elements in the fashion claimed by the application, the analysis should be made explicit. *See KSR* (citing *In re Kahn*, 441 F.3d 977, 988 (CA Fed. 2006) ("[R]ejections on obviousness grounds cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning within some rational underpinnings to support the legal conclusion of obviousness.").

The Examiner's obviousness analysis, which was prepared before the *KSR* opinion was handed down by the Supreme Court, apparently applied only the old "*prima facie* case" test of *In re Vaeck*, and therefore did not include a *Graham v. Deere* analysis, including a discussion of the reason why a person of ordinary skill in the art would have combined the cited prior art elements. Accordingly, the Applicant respectfully requests that the Examiner withdraw the obviousness rejections and reconsider the application in light of the *KSR* opinion.

However, even under the old "*prima facie* case" test of *In re Vaeck*, in light of the amendments to the claims, the claims are not obvious over the references cited.

Obviousness Analysis Pursuant to the Old *Prima Facie* Case of *In re Vaeck*

Section 706.02(j) of the MPEP sets forth the old requirements for establishing the *prima facie* case of obviousness as follows:

> To establish a *prima facie* case of obviousness, three basic criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art and not based on the applicant's disclosure. *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed. Cir. 1991).

In this case, none of Freeberg, Schmid, Mukasa, Discko, and Fletcher, or any combination thereof, teach or suggest all the claim limitations of the claims in light of the amendments to claims 1 and 9.

Claims 1–3, 5, 6, 9–11, 14, and 15 – Freeberg

The Examiner rejected claims 1–3, 5, 6, 9–11, 14, and 15 under 35 U.S.C. § 103(a) as being unpatentable (obvious) over the combination hypodermic syringe and mixing container described in United States Patent Number 3,327,710 (the Freeberg patent).

Claim 5 was previously canceled.

As to the pending claims, as previously discussed, claim 1, from which claims 2, 3, and 6 depend, either directly or indirectly, and claim 9, from which claims 10, 11, 14, and 15 depend, either directly or indirectly, have been amended to include the limitation that the calibrated puncturing device be "configured so as to not be attached to said ampule when dispensing" said quantity of medication (claim 1) or said suspension (claim 9) from the ampule.

Freeberg describes a device in which depression of a plunger pushes a diaphragm against the pointed portion of a hypodermic needle and ruptures the diaphragm to permit intermixing of materials. (*Freeberg*, Col. 2: lns. 15–19.) Of course, the hypodermic needle is the conduit

through which the medication or mixture of materials is dispensed. Accordingly, the puncturing device of Freeberg is necessarily attached to the "ampule" containing the medication or mixture to be dispensed when dispensing the medication or mixture from the ampule. Thus, Freeberg does not teach or suggest the limitation of claims 1–3, 6, 9–11, 14, and 15 of having a puncturing device configured so as to not be attached to the ampule when dispensing the medication or suspension from the ampule. For this reason, the Applicant respectfully contends that, in light of the amendments to claims 1 and 9, even under the old *prima facie* case of obviousness of *In re Vaeck*, claims 1–3, 6, 9–11, 14, and 15 are not obvious over Freeberg.

Claims 6, 8, 14, and 16 – Freeberg and Schmid

The Examiner rejected claims 6, 8, 14, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Freeberg in view of the calcium hydroxide package and method of forming same described in United States Patent Number 5,819,921 (the Schmid patent).

The rejected claims depend from either claim 1 or claim 9, either directly or indirectly, and therefore include the limitations of claims 1 and 9 as amended, particularly the limitation that the calibrated puncturing device be "configured so as to not be attached to said ampule when dispensing" said quantity of medication (claim 1) or said suspension (claim 9) from the ampule. As previously discussed, Freeberg does not teach or suggest this limitation.

Similarly, Schmid does not teach or suggest this limitation. The device described in Schmid does not require any puncturing to gain access to a liquid or suspension to be dispensed. Accordingly, it does not suggest having a puncturing device configured so as to not be attached to an ampule when dispensing medication or suspensions from the ampule.

For the foregoing reasons, Freeberg and Schmid, when combined, do not teach or suggest all the claim limitations of claims 6, 8, 14, and 16, in light of the amendments to claims 1 and 9. Accordingly, the Applicant respectfully contends that claims 6, 8, 14, and 16 are not obvious over Freeberg in view of Schmid.

Claims 6, 8, 14, and 16 – Mukasa and Discko

The Examiner also rejected claims 6, 8, 14, and 16 under 35 U.S.C. § 103(a) as being unpatentable over Mukasa in view of the single patient dose dental cartridge tray and organization system described in United States Patent Number 5,199,567 (the Discko patent).

The rejected claims depend from either claim 1 or claim 9, either directly or indirectly, and therefore include the limitations of claims 1 and 9 as amended, particularly the limitation that the calibrated puncturing device be "configured so as to not be attached to said ampule when

dispensing" said quantity of medication (claim 1) or said suspension (claim 9). As previously discussed, Mukasa does not teach or suggest this limitation.

Similarly, Discko does not teach or suggest this limitation. The device described in Discko apparently does not require any puncturing to gain access to the material to be dispensed. Accordingly, it does not suggest having a puncturing device configured so as to not be attached to an ampule when dispensing medication or suspensions from the ampule.

For the foregoing reasons, Mukasa and Discko, when combined, do not teach or suggest all the claim limitations of claims 6, 8, 14, and 16, in light of the amendments to claims 1 and 9. Accordingly, the Applicant respectfully contends that claims 6, 8, 14, and 16 are not obvious over Mukasa in view of Discko.

Claims 1–3 – Fletcher

The Examiner rejected claims 1–3 under 35 U.S.C. § 103(a) as being unpatentable over the single dose medicament dispenser assembly described in United States Patent Number 5,609,581 (the Fletcher patent).

As previously discussed, claim 1, from which claims 2 and 3 depend, either directly or indirectly, has been amended to include the limitation that the calibrated puncturing device be "configured so as to not be attached to said ampule when dispensing said quantity of medication from said ampule." Fletcher does not teach or suggest this limitation.

Fletcher describes a combination of an applicator having an internal piercing element and a container with a puncturable diaphragm at one end in which the applicator is connected to the container in such a way that the internal piercing element of the applicator punctures the diaphragm "to permit discharge of the contents through the piercing element and the discharge openings in the applicator." (*Fletcher*, Abstract.) Accordingly, Fletcher teaches and suggests a device in which the puncturing device is configured so as to be *attached* to an ampule when dispending the quantity of medication contained therein. Thus, Fletcher does not teach or suggest the limitation of claims 1–3 of having a puncturing device configured so as to *not be attached* to the ampule when dispensing the medication or suspension. For this reason, the Applicant respectfully contends that, in light of the amendments to claim 1, even under the old *prima facie* case of obviousness of *In re Vaeck*, claims 1–3 are not obvious over Fletcher.

Conclusion

None of the amendments made herein add new matter.

If the Examiner feels it would advance the application to allowance or final rejection, the Examiner is invited to telephone the undersigned at the number given below.

Reconsideration and allowance of the application as amended is respectfully requested.

DATED this 5th day of July, 2007.

Very respectfully,

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CERTIFICATE OF MAILING

I HEREBY CERTIFY that this correspondence is being electronically deposited with the United States Patent Office via the EFS-Web on the below date as addressed to:

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Julie O'Tyson
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